

June 08, 2005 - Remarks on Over the Counter Emergency Contraceptive Rule for H.R. 2744, Agriculture, Rural Development, FDA & Related Agencies Appropriations Act, 2006

Mr. Speaker, as we debate the agriculture appropriations bill today, we will consider funding for the Food and Drug Administration. I am very disappointed that the Hinchey FDA reform amendment will not be allowed under this rule. The amendment would give the Food and Drug Administration two new authorities that are badly needed to improve the FDA's drug safety operations and ensure that FDA has the tools to take timely action to protect Americans from unsafe drugs.

It would have empowered the FDA with the authority to require companies to conduct post-marketing studies of FDA-approved drugs and would also have given the FDA the authority to mandate changes to the labels of FDA-approved drugs. Unfortunately, efforts to include the amendment were defeated in the Committee on Rules on a party-line vote.

I am deeply concerned about the FDA's handling, or rather their mishandling, of the consideration to allow emergency contraception to be sold over the counter. For almost 100 years, the FDA has overseen the safety of food, cosmetics, drugs, and medical devices consumed by the American public, but we cannot trust them unconditionally any more.

The agency defines itself as a scientific, regulatory and public health agency. But for what appears to be the first time in the agency's history, the FDA has jettisoned the rigorous standards of science and health in evaluating emergency contraception and has instead taken the counsel of religious and political extremists in its consideration of this important pregnancy-preventive drug.

And the results of such counsel have been predictable. Despite the fact that 23 of 27 members of the FDA's advisory panel voted in favor of allowing over-the-counter sales of Barr Laboratories' Plan B emergency contraceptive and despite the overwhelming scientific evidence

in support of the application, the FDA made the unusual decision to disregard its own advisory panel's recommendation and reject the application.

One of the dissenting panelists was evangelical conservative Dr. W. David Hager. In October of 2002, I sent a letter to President Bush expressing my deep reservations about appointing Dr. Hager as Chair of the Advisory Committee for Reproductive Health Drugs at the FDA. Based on Dr. Hager's past conduct, I believed he would not be impartial in his decisions. On numerous occasions, Dr. Hager had already displayed a willingness to substitute his personal beliefs for science. My request, unfortunately, went unheeded by the administration.

Now recent reports have alleged that the FDA, while considering allowing over-the-counter sales of emergency contraceptive, requested a minority opinion by Dr. Hager to justify a politically motivated decision to Barr Laboratories' application, a truly outrageous request which, if true, has further jeopardized the scientific integrity of the FDA.

Clearly the standards of science and the interest of public health have taken a back seat to the political agenda of extremist politicians.

The scientific facts irrefutably show that emergency contraception is a safe and effective way for women to prevent unintended pregnancies. Emergency contraception has been available in the United States by prescription since the late 1990s. It does not cause abortion. Instead, it stops the release of the eggs from the ovary and prevents unwanted pregnancy. If preventing unwanted pregnancy is something we support, no matter what our individual positions are on a woman's reproductive freedom, we should be outraged by this lack of science behind this decision.

Effectively preventing unwanted pregnancies is clearly the best way to reduce the number of abortions, and if my colleagues care about that, they must recognize this fundamental truth.

The Alan Guttmacher Institute estimates that increased use of emergency contraceptives accounted for up to 43 percent of the total decline in abortions between 1994 and the year 2000. In addition, emergency contraception is often the only option for the 300,000 women who are raped each year. It is widely recognized as an integral part of comprehensive and compassionate emergency treatment for sexual assault survivors.

The bottom line here is that over-the-counter approval is the single most effective tool we have to reduce unwanted pregnancies in America, but one man is holding it up. Anyone really serious about reducing the number of abortions will support making it available. There are two only sides of this line Members can be on. They either want to stop apportionments or reduce them, or they do not.

As we await again a decision on Barr Laboratories, a decision the FDA promised in January but has not given us yet, I urge them to base this and future decision on science, not politics. It is time the FDA recognizes it must be more accountable to the American public to make the best decisions possible based on scientific evidence which is what they are for. They just do not do that anymore.